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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,132	01/25/2002	Hiroaki Nishiuchi	218070US0PCT	8138

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EXAMINER	
MARX, IRENE	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 03/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,132	NISHIUCHI ET AL.	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *03 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-6 and 9* is/are pending in the application.

4a) Of the above claim(s) *6* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-5 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The amendment filed 2/3/04 is acknowledged. Claims 1,4,5 and 9 are being considered on the merits.

Rejections under 35 U.S.C § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-5 and 9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention now is directed to strains of *Saccharomyces cerevisiae* having specific properties. It is not clear if the written description is sufficiently repeatable to avoid the need for a deposit. Further it is unclear if the starting materials were readily available to the public at the time of invention,.

It appears that no deposit was made in this application that meets all of the criteria set forth in 37 CFR 1.801-1.809. Applicant or applicant's representative may provide assurance of compliance with the requirements of 35 U.S.C § 112, first paragraph, in the following manner.

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

1. Identifies declarant.

2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.

3. States that the deposited material has been accorded a specific (recited) accession number.

4. States that all restriction on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

5. States that the material has been deposited under conditions that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C § 122.

6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit for the enforceable life of the patent, whichever period is longer.

7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

Claims 1, 4-5 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a *Saccharomyces cerevisiae* which produces 1% or more of γ-glutamylcysteine and 0.004-0.1% by weight of glutathione during its logarithmic growth phase in a minimal medium. In contrast, the specification only provides guidance obtaining strains which are at least auxotrophic for uracil and need this material in the medium at a specific concentration. The only strains which meet the claim designated requirements of production of certain materials appear to be Nα3 No. 1 and No. 2 (Table 1.). These strains are

disclosed to produce 0.0043 and 0.0045 % glutathione. However, these strains fail to do so in minimal media. Therefore, claims 1 and 5 lack an adequate written description in the specification as filed.

In addition, it is uncertain whether even one of these strains produces glutathione synthetase of which amino acid residues of the 370th position and thereafter are deleted and under which conditions. Therefore, it cannot be readily ascertained whether an adequate written description is provided even for any strain meeting the requirements of claim 4 and 9.

In addition, no strains as claimed appear to be readily available to the public as required by the statute.

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the claimed invention.

See University of California v. Eli Lilly and Co., 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

See Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene (or promoter) is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence), and at page 1027, where it is taught that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is vague, indefinite and confusing in the recitation of "which produces glutathione synthetase of which amino acid residues of the 370th position and thereafter are deleted". It is unclear what is intended in this context, since it is not apparent that all glutathione synthetase synthetases have the same sequence.. The recitation at "the 370th position and thereafter" renders the claim confusing, since the nucleotide sequence(s) having this deletion is/are not identified with any specificity and there is no clear point of reference as to the position intended.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

The argument by counsel that only one amino acid sequence of glutathione synthase from *Saccharomyces cerevisiae* is known is noted. The arguments by counsel in this regard have not been substantiated with appropriate evidence. It is well settled that arguments by counsel do not constitute evidence. In addition that one sequence of this type is registered as Accession No. Q08220 in the SwissProt database does not define the invention as claimed. Revisions or updates to SwissProt entries can be made at any time. Moreover, the claim designated invention does not pertain to any particular or specific glutathione synthetase.

Therefore the rejection is deemed proper and it is adhered to.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

.This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5 and 9 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ohtake *et al.*.

The claims are directed to a yeast extract of *S. cerevisiae* strain that contains 1% or more glutamylcysteine and which contains 0.004%-0.1% by weight of glutathione.

Ohtake *et al.* disclose an *S. cerevisiae* yeast extract that contains 1% or more glutamylcysteine and which contains 0.004%-0.1% by weight of glutathione. See, e.g., Table III. An extract of the cells was prepared to measure intracellular contents. See, e.g. page 3147, first paragraph.

The composition is claimed as a product-by-process. Since the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of prima facie anticipation/obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113.

It is reasonable to assume on this record that the yeast extract is identical or substantially identical to that claimed. Accordingly, the burden of going forward is reasonably shifted to applicant. The fairness of this is evidenced by the U.S. Patent and Trademark Office's inability to manufacture or to obtain products and compare them with those claimed. See, In re Best, 195 USPQ 430, (CAFC 1977).

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicants argue the method of making of the product. However, this is not relevant for a product by process claim, wherein the material examined is the product *per se.*

Claims 5 and 9 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sugiyama *et al.*.

The claims are directed to a yeast extract of *S. cerevisiae* strain that contains 1% or more glutamylcysteine and which contains 0.004%-0.1% by weight of glutathione.

Sugiyama *et al.* disclose an *S. cerevisiae* yeast extract that contains 1% or more glutamylcysteine and which contains 0.004%-0.1% by weight of glutathione. See, e.g., Figure

III. An extract of the cells was prepared to measure intracellular contents. See, e.g. page 15536, col. 1.

The composition is claimed as a product-by-process. Since the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of prima facie anticipation/obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113.

It is reasonable to assume on this record that the yeast extract is identical or substantially identical to that claimed. Accordingly, the burden of going forward is reasonably shifted to applicant. The fairness of this is evidenced by the U.S. Patent and Trademark Office's inability to manufacture or to obtain products and compare them with those claimed. See, In re Best, 195 USPQ 430, (CAFC 1977).

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicants argue the method of making of the product. However, this is not relevant for a product by process claim, wherein the material examined is the product *per se.*

Applicant has not demonstrated any differences in the properties of the yeast extract product claimed as a product-by-process and the product of the references.

Therefore the rejection is deemed proper and it is adhered to.

Claims 5 and 9 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kuroda *et al.* (JP04066069).

The claims are drawn to a yeast extract composition which has been obtained by a certain process and which contains glutathione.

The cited reference discloses a yeast extract composition which contains glutathione which appears to be identical to the presently claimed yeast composition (see, e.g., Abstract) since it similarly was extracted from *S. cerevisiae* and contains the required compounds. The referenced yeast composition appears to be identical to the presently claimed yeast composition and is considered to anticipate the claimed yeast composition since it contains the same

ingredients. Consequently, the claimed yeast composition appears to be anticipated by the reference.

In the alternative, even if the claimed yeast composition is not identical to the referenced yeast composition with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced yeast composition is likely to possess the same characteristics of the claimed yeast composition particularly in view of the similar characteristics which they have been shown to share. Thus the claimed yeast composition would have been obvious to those skilled in the art within the meaning of USC 103.

Furthermore, the composition is claimed as a product-by-process. Since the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of prima facie obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant argues that Kuroda do not suggest the present invention because they do not disclose a specific yeast strain containing glutathione and γ-glutamylcysteine. With all due respect it is noted that the presently claimed invention is not directed to a specific yeast strain containing glutathione and γ-glutamylcysteine. Applicant goes on the discuss theoretical considerations about activation and inactivation of genes. However, applicant has not demonstrated any differences in the properties of the yeast extract product claimed as a product-by-process and the product of the references.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Irene Marx
Primary Examiner
Art Unit 1651